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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,305	06/06/2002	Gene H MacDonald	5470.276	1963
20792 7590 04/13/2009 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER				
ANGELL, JON E				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
04/13/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/069,305

Applicant(s)

MACDONALD ET AL.

Examiner

J. E. Angell

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30 is/are rejected.
- 7) ☒ Claim(s) 31 and 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Action is in response to the communication filed on 1/27/2009.

The amendment filed 1/27/2009 is acknowledged and has been entered.

Claims 27-32 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/32733 (Johnston et al., previously of record) in view of Gould et al. (J. Gen. Virol., 1989; Vol. 70, pages 1605-1608).

Johnston et al. teach a method wherein an VEE virus which encodes and expresses a heterologous immunogen is administered to a subject as a vaccine to protect the subject against disease wherein the subject can be a human (e.g. see abstract; page 2, lines 17-30; page 6 line 30 through page 7, line 25).

Johnston et al. do not teach to administer an antibody that specifically binds to the E1 glycoprotein of the VEE along with the VEE.

Gould teaches antibody dependent enhancement of Yellow Fever (YF) and Japanese Encephalitis virus (JEV) neurovirulence when monoclonal antibodies specific for E glycoprotein of the infecting virus is administered to a subject 3 days after administration of the virus (e.g., see abstract, Tables 1-3, etc.).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Johnston et al. and Gould et al. to create a method of using E1 glycoprotein specific antibodies with an VEE that comprises a heterologous sequence, wherein the antibody is administered subsequent to administration of the VEE in order enhance the infectivity of the VEE in a subject, including to a human with a reasonable expectation of success.

The motivation to combine the references to create claimed invention and is provided by Gould who teaches that administration of E-glycoprotein monoclonal antibodies 3 days after administration of YF or JEV enhance the infectivity of the virus. Furthermore, the fact that the antibodies enhanced infectivity of the YF and JEV virus in mice demonstrates a reasonable expectation of success that infectivity of the Encephalitis virus taught by Johnston et al. could be enhanced in a subject, including a human, without causing significant pathology.

Response to Arguments

2. Applicant's arguments, filed 1/27/09, with respect to the rejection of claims under 35 U.S.C. 112, first paragraph have been fully considered and are persuasive. Accordingly, the rejection has been withdrawn.

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3. Applicant's arguments filed 1/27/09 with respect to the rejection of claims 27-30 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

4. Applicants argue that one of ordinary skill in the art would not have been motivated to make the claimed invention, nor would there have been a reasonable expectation of success, based on the teachings of Gould. Applicants contend that the teaching by Gould that ADE was not seen in all flaviruses tested demonstrates that there would not have been any reasonable expectation of success. Applicants also argue that that the Examination Guidelines and the KSR decision indicate that the touchstones for obviousness are predictability and reasonable expectation of success. In response, one of ordinary skill in the art would have been motivated to combine the teachings of the cited references to make the claimed invention based on the teaching of Gould that administration of E-glycoprotein monoclonal antibodies 3 days after administration of YF or JEV enhance the infectivity of the virus. Thus, Gould provides the required motivation to make and use the claimed invention. Furthermore, the fact that Gould teaches that administration of E-glycoprotein monoclonal antibodies enhanced the infectivity of both YF or JEV virus provides a *reasonable* expectation that using an antibody specific for the E-glycoprotein of VEE in combination with a VEE vector would successfully increase the infectivity of the VEE vector. It is respectfully pointed out that an absolute expectation of success is not required, only a *reasonable* expectation of success. In the instant case, Gould provides a proper basis for a *reasonable* expectation of success. It is also noted that an argument that there is not a reasonable expectation of success could also be interpreted as an assertion that the claimed method represents an

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unexpected result. With respect to any potential unexpected results (implied or not), it is noted that MPEP 716.01(c) makes clear that:

“The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.”

In the instant case, the arguments of unexpected results are not supported by an appropriate affidavit or declaration. Therefore, Applicants arguments are not persuasive.

Claim Objections

5. Claims 31 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635